



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

22/SEP/2010

MEMORANDUM

Subject: Name of Pesticide Product: Apivar Strips
EPA Reg. No. /File Symbol: 87243-R
DP Barcode: D373624
Decision No: 425434
Action Code: R170
PC Code: 106201 (amitraz)

From: Eugenia McAndrew, Biologist
Technical Review Branch
Registration Division (7505P)

E. McAndrew
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To: John Hebert/Autumn Metzger, RM Team 07
Insecticide-Rodenticide Branch
Registration Division (7505P)

Applicant: Veto-Pharma
14 Avenue du Quebec
91140 Villbon sur Yvette, France

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Amitraz	3.3

<u>Inert Ingredient(s):</u>	<u>96.7</u>
Total:	100.0%

ACTION REQUESTED: The Risk Manager requests: "Please review the attached acute toxicity waiver request (see page 4 of document), submitted in support of 87243-R, an insecticide containing 3.3% amitraz. Copies of the submission cover letter, CSF and label are included."

BACKGROUND: Veto-Pharma has applied for registration of Apivar Strips, EPA File Symbol 87243-R, a new product containing 3.3% amitraz for use in controlling varroa mites in bee hives. As part of the application, the registrant has also submitted a petition for the establishment of tolerances for amitraz in honey.

The registrant is requesting a waiver from the requirement for acute toxicity testing for this proposed product. To support this request, the registrant has provided a document titled "Avitar Strips - Acute toxicity Dietary Risk Assessment." From page 4 of this document:

Amitraz will be present at a concentration of 3.3% in a plastic strip that consists only of a copolymer that is exempt from the need of a tolerance at 40 CFR 180.960. The US EPA Re-registration Eligibility Document (RED) for amitraz notes that the acute oral and dermal toxicities of the amitraz TGAI are Toxicity Category III and Toxicity Category II, respectively. Amitraz is non-irritating to the skin and eyes (Toxicity Category IV). Amitraz does not cause skin sensitization. Inhalation toxicity of the TGAI is Toxicity Category III but no inhalation exposure is expected with this end use product of amitraz. For labeling purposes, it is recommended that warning phrases be based upon toxicity observed with the amitraz TGAI.

Veto-Pharma and Arysta Lifescience America, Inc. request that EPA rely upon the acute toxicity data generated for amitraz technical and waive the need for any additional acute toxicity data to support the registration of the Apivar Strips.

A data matrix citing acute oral MRID (00041539), acute dermal (MRID 00040862), acute inhalation (MRID 00029963), primary eye irritation (MRID 00040861), primary skin irritation (MRID 00040862) and dermal sensitization (MRID 00029965) studies is included in the submission. These studies are the exact studies that were used to characterize the acute toxicity profile of amitraz in the Agency Reregistration Eligibility Decision (RED) signed on March 3, 1995. The following table is from page 8 of the RED:

Test	Results LD ₅₀	MRID No.	Category
(81-1) Oral LD ₅₀ - rat	531 mg/kg (M) 515 mg/kg (F)	00041539	III
(81-2) Dermal LD ₅₀ - rat	> 200 mg/kg	00040862	II
(81-3) Inhalation LC ₅₀ - rat	2.4 mg/L	00029963	III*
(81-4) Eye Irritation - rabbit	Non-irritating	00040861	IV
(81-5) Dermal Irritation - rabbit	Non-irritating	00040862	IV
(81-6) Dermal Sensitization - guinea pig	Negative	00029965	N/A

*Category IV by today's standards

The registrant also submitted a proposed label with the signal word WARNING and precautionary labeling that is appropriate for the toxicity categories assigned to the cited studies.

RECOMMENDATIONS:

1. TRB has reviewed the registrant's request to waive the requirement for acute toxicity testing for the proposed product, Apivar Strips, EPA File Symbol 87243-R. TRB agrees that if the registrant is willing to accept the acute toxicity profile of amitraz technical for the proposed product, then the studies cited from technical amitraz can support the registration of 87243-R and no additional acute toxicity data will be required.

2. The acute toxicity profile for the proposed product, Apivar Strips, EPA File Symbol 87243-R, is as follows:

acute oral toxicity	III	cited	MRID 00041539
acute dermal toxicity	II	cited	MRID 00040862
acute inhalation toxicity	IV	cited	MRID 00029963
primary eye irritation	IV	cited	MRID 00040861
primary skin irritation	IV	cited	MRID 00040862
dermal sensitization	negative	cited	MRID 00029965

3. The proposed basic CSF dated December 22, 2009 must be approved by the TRB Product Chemistry Team.

LABELING: Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System:

PRODUCT ID #: 087243-00001

PRODUCT NAME: Apivar Strips

PRECAUTIONARY STATEMENTS

SIGNAL WORD: WARNING

Hazards to Humans and Domestic Animals:

May be fatal if absorbed through skin. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

First Aid:

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

Note: The proposed label does contain handler PPE to address the Category II acute dermal toxicity.